Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Elastoplast Back Pain 4.8 mg Medicated Plaster.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each plaster contains 112 - 167 mg soft extract of cayenne pepper (4-7:1) corresponding to 4.8 mg capsaicinoids, calculated as capsaicin. Extract solvent is ethanol 80% (v/v).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Plaster
Rectangular perforated plaster (18x12 cm) with viscose fabric carrier.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To be used externally for the relief of muscle pain, e.g. lower back pain.

4.2 Posology and method of administration

Posology

Adults
A maximum of 1 plaster per day and should be left in place for at least 4 and up to 8 hours.
There should be an interval of at least 12 hours before a new plaster is applied on the same application area.

New plasters should be applied until the pain subsides, if necessary, up to 3 weeks duration.

Children
Elastoplast Back Pain 4.8 mg Medicated Plaster is not recommended for use in children below 12 years of age due to a lack of clinical data on safety and efficacy.

Elderly
No dose adjustment is necessary if Capsicum 4.8 mg medicated plaster is used in the elderly.

Hepatic and renal impairment
No dose adjustment is necessary if Capsicum 4.8 mg medicated plaster is used in patients with hepatic or renal impairment.

Method of administration
The plaster is intended for cutaneous use.
The covering paper is peeled off and the plaster applied to dry, unbroken skin directly over the painful area with adhesive side to the skin.

To remove the plaster, one corner is raised and the plaster is carefully pulled off.

Any remnants remaining on the skin after detachment of the plaster can be removed with vegetable oil, a moisturising cream or cold water.

Hands should be washed with soap and water after touching or handling the plaster.

4.3 Contraindications

The plaster is contraindicated:
- in individuals with hypersensitivity to cayenne pepper, to other capsaicinoid sources (e.g. paprika plants) or to any of the excipients listed in section 6.1;
- on broken skin and wounds and eczema.

4.4 Special warnings and precautions for use

The plaster should not be applied near the eyes or to mucous membranes.

It is recommended not to scratch the application site to avoid damage to the skin.

Application of additional sources of heat during treatment should be avoided (e.g. solar or infrared radiation, heating pad or warm water). The effect of warmth can also be intensified by physical activity (sweating): Treatment should be discontinued if the heat effect is experienced as excessive. In this case the plaster should be removed.

This medicinal product contains wool fat (lanolin). Wool fat may cause local skin reactions (e.g. contact dermatitis).

Advice given to the patient in the package leaflet:
You should consult a physician before administration of the plaster, if one of the following symptoms applies to you:
- severe cases accompanied by reddening, swelling or hyperthermia of joints,
- ongoing joint trouble or severe back pain radiating into the legs and/or are associated with neurological syndromes (e.g. numbness, tingling).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

The plaster is not intended to be applied at the same time as other products [e.g. other rubefacients (which increase the perfusion and cause a reddening of the skin) or pain relieving gels] at the same application site.

Interactions with other products applied at the same application site may even occur several hours after the plaster has been removed.

4.6 Fertility, pregnancy and lactation

There are no data from the use of Elastoplast Back Pain 4.8 mg Medicated Plaster in pregnant women. Studies in animals have shown reproductive toxicity after high subcutaneous doses of capsaicin (see section 5.3). Capsaicin crosses the placenta and may pass into breast milk.

Although, prenatal and neonatal effects of capsaicin occurred at doses in excess of the maximum clinical dose of Elastoplast Back Pain 4.8 mg Medicated Plaster, these plasters should only be used during pregnancy and lactation after a careful risk-benefit assessment.

No fertility data are available.

4.7 Effects on ability to drive and use machines

There is no reason to believe that the use of Elastoplast Back Pain 4.8 mg Medicated Plaster will impair the ability to drive or use machines.

4.8 Undesirable effects

The active ingredient of the plaster, soft extract of cayenne pepper, causes increased blood circulation with reddening the of the skin and a sensation of warmth. This reaction is part of the normal pharmacological action of the preparation and subsides as a rule within a short time after removal of the plaster.

In rare cases (≥1/10,000 to <1/1,000):
Skin hypersensitivity and allergic reactions (e.g. urticaria, blisters or vesiculation) may occur at the application site. The treatment should be stopped in such cases immediately.

If during the first days of treatment a burning sensation or any stinging or itching occurs which is excessive, treatment should be discontinued.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the HPRA Pharmacovigilance
Earlsfort Terrace IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie,
e-mail: medsafety@hpra.ie.

4.9 Overdose

Due to the special characteristics of the plaster overdosage is extremely unlikely. Symptoms of overdose would be expected to comprise exaggerated reactions as described in section 4.8. When exaggerated reactions occur treatment should be discontinued. If required, a symptomatic treatment should be initiated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Capsicum preparations and similar agents, ATC-Code: M02AB

Mechanism of action
Capsaicin is the primary pungent principle in the fruit of capsicum plants.The precise mechanism of action has not been fully elucidated.

Pharmacodynamic effects
Topically applied capsaicin triggers local irritation, which manifests symptomatically as erythema and a burning, sometimes itchy, sensation. This is generally attributed to a neurogenic inflammatory process and explained by the release of the neurotransmitter substance P. A clinical trial carried out with Elastoplast Back Pain 4.8 mg Medicated Plaster has shown that capsaicin can induce erythema and initial sensation of heat, sometimes in combination with itching.

The second stage of the capsaicin action is associated with antinociceptive effects the duration of which ranges from hours to weeks. Substance P depletion of the neurone following repeated application leads to a long-term desensitisation to burning and pain.

5.2 Pharmacokinetic properties

Absorption and distribution
In vitro release studies with Elastoplast Back Pain 4.8 mg Medicated Plaster have demonstrated that the amount of capsaicin released during application lasting up to 8 hours (approximately 35% of capsaicin content) is able to produce an analgesic effect in clinical and preclinical studies.
Animal data suggest a systemic bioavailability of topically applied capsaicin
ranging from 27 to 34%.

The absorption rate of capsaicin through skin is consistent with values found in the published literature for topically

applied semisolid preparations.
In vitro studies have demonstrated, that capsaicin is absorbed percutaneously. The absorption rate through excised rat skin ranged from 7 to 11µg/cm²/h.

The absorbed capsaicin is metabolised mainly in the liver and eliminated in the form of metabolites in the urine and faeces.

5.3 Preclinical safety data

Acute toxicity of capsaicin in mice was in the order intravenous > intraperitoneal > subcutaneous > oral > dermal indicating that systemic absorption and toxicity following dermal application were lower than after an oral dose.
High subcutaneous doses of capsaicin were not teratogenic in rats. However, there was evidence that capsaicin crosses the placenta and exerts a toxic effect on the peripheral nerves of fetuses, provoking extensive depletion of substance P immunoreactive nerve fibre from the dorsal horn of the spinal cord.

Prenatal treatment of rats with high subcutaneuos doses of capsaicin (50 mg/kg) caused functional neuronal defects; whereas neonatal treatment retarded body growth and sexual maturation, decreased mating frequency and reduced gestations.
Published data on potential mutagenicity and carcinogenicity of capsaicin were inconclusive.
Capsaicin, in the quantities absorbed cutaneously from Elastoplast Back Pain ***Medicated Plaster***, is unlikely to pose any significant hazard to humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid glucose
purified water
2,2'-methylene-bis-(6-tert-butyl-4-methylphenol)
2,2'-(propane-1,2-diyldiiminodimethyl) diphenol
Orris root powder/rice flour mixture
Caoutchouc
Poly(butadiene-block-styrene) (76.5:23.5)
Cis-1,4-polyisoprene
Talcum
Beta pinene homopolymer
Poly (2-methylbut-2-ene-co-penta-1,3-diene)
Glycerol ester of hydrogenated colophony
Light liquid paraffin
Wool fat
Viscose fabric (plaster carrier)
Paper siliconised on one side (covering paper)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years as packaged for sale.
Shelf-life after first opening the sachet: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Sachet made of paper/polyethylene/aluminium/Surlyn laminated material, sealed with 1 or 2 medicated plasters.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

After removal the plaster should be placed in a plastic bag, which is to be sealed securely and disposed of via household waste.

7 MARKETING AUTHORISATION HOLDER

Beiersdorf AG
Unnastrasse 48
20245 Hamburg
Germany

8 MARKETING AUTHORISATION NUMBER

PA 1106/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 May 2004

Date of last renewal: 25 October 2007

10 DATE OF REVISION OF THE TEXT

January 2015